

UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF MICHIGAN  
SOUTHERN DIVISION

LG SCIENCES, LLC,

Plaintiff,

No. 11-cv-10830

vs.

Hon. Gerald E. Rosen

JUDITH PUTZ, Compliance Officer,  
Food & Drug Administration,  
sued in her individual capacity,

Defendant.

OPINION AND ORDER GRANTING  
DEFENDANT'S MOTION TO DISMISS

At a session of said Court, held in  
the U.S. Courthouse, Detroit, Michigan

on March 30, 2012

PRESENT: Honorable Gerald E. Rosen  
United States District Chief Judge

I. INTRODUCTION

This *Bivens* action<sup>1</sup> is presently before the Court on Defendant's Fed. R. Civ. P. 12(b)(6) Motion to Dismiss Plaintiff's Complaint for failure to state a claim upon which relief may be granted. Plaintiff has responded to Defendant's motion and Defendant has replied. Having reviewed and considered Defendant's motion, the parties' briefs and the

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<sup>1</sup> *Bivens v. Six Unknown Named Agents of the Federal Bureau of Narcotics*, 403 U.S. 388 (1971).

entire record of this matter, the Court has determined that oral argument is not necessary. Therefore, pursuant to Eastern District of Michigan Local Rule 7.1(f)(2), this matter will be decided on the briefs. This Opinion and Order sets forth the Court's ruling.

## II. FACTUAL BACKGROUND

Plaintiff LG Sciences, LLC ("LG") is a Michigan limited liability company specializing in the manufacture of dietary and sports supplements. Defendant Judith Putz is a Compliance Officer with the United States Food and Drug Administration (the "FDA"). On April 2, 2008, the United States filed a Complaint for Forfeiture alleging that certain products labeled "dietary supplements" which were manufactured by LG and stored at its facility in Brighton, Michigan were "adulterated" within the meaning of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 330, *et seq.* See *United States of America v. 605 Cases, More or Less, of an Article of Food, Each Case Containing 12/135 Capsule Bottles, et al.*, No. 08-CV-11395-NGE (the "Forfeiture Action"). Specifically, in the Forfeiture Complaint, the Government alleged that the products contained the chemical compound 1, 4, 6-etioallocholan-dione ("ATD") and a portion of the products contained the chemical compound 4-etioallocholan-3, 6, 17-trione ("6-OXO"), and alleged that both ATD and 6-OXO were either unapproved food additives or new dietary additives for which inadequate information existed to provide a reasonable assurance that they did not present a significant risk of illness or injury. See Forfeiture Complaint, ¶¶ 2a-2c; 15-17. Because LG continued to market products containing ATD and 6-OXO despite the FDA's warnings, the Government requested that the Court order the seizure,

condemnation, and destruction of the products. *Id.*, p. 6. The Complaint was verified by Judith Putz, who stated in her verification

I, Judith A. Putz, Compliance Officer for the Food and Drug Administration, U.S. Department of Health and Human Services, have read the Complaint for Forfeiture in this action and that its contents are true and correct to the best of my knowledge, information and belief.

*See id.*, Forfeiture Complaint Verification, p. 8.

LG intervened in the Forfeiture Action as “owner and claimant” of the articles identified for seizure and condemnation, and filed an Answer with Affirmative Defenses and a Counterclaim. *See* Forfeiture Action, Dkt. Nos. 2 and 3. In its Answer with Affirmative Defenses, LG asserted:

5. 1,4,6 Etioallocholan-Dione meets the statutory definition of a dietary ingredient as defined in 21 U.S.C. 321(ff).
6. Neither 1,4,6 Etioallocholan-Dione nor 4-Etioallocholen-3,6,17-Trione are unapproved food additives as both are dietary ingredients and are excluded from being deemed food additives pursuant to 21 U.S.C. §348.
7. Neither ingredient is a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury under 21 U.S.C. §342(f)(1)(B).
8. Even if either ingredient were deemed to be a new dietary ingredient, there is adequate “information to provide reasonable assurance that such ingredient[s] do[] not present a significant or unreasonable risk of illness or injury.” 21 U.S.C. §342(f)(1)(B).
9. Both 1,4,6 Etioallocholan-Dione 4-Etioallocholen-3,6,17-Trione are “generally recognized, among experts qualified by scientific training and experience to evaluate [their] safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience

based on common use in food) to be safe under the conditions of [their] intended use.” 21 U.S.C. §321(s) .

[See LG’s Answer and Affirmative Defenses, Forfeiture Action Dkt. #3, Affirmative Defenses, ¶¶ 5-9.]

On May 11, 2009, the United States and LG entered into a Consent Decree of Condemnation and Destruction in the Forfeiture Action in which LG agreed to destroy the identified products under the supervision of the FDA. See Forfeiture Action, Dkt. # 24. LG complied with the terms of the Consent Decree , and the case was closed. See *id.*, Dkt. # 25.

On March 1, 2011, LG, through new counsel, filed the instant *Bivens* action alleging that its Fourth Amendment right not to be subjected to an unreasonable search and seizure had been violated by Defendant Putz. The basis for this claim is LG’s contention that at the time that Defendant Putz verified the Complaint for Forfeiture she “knew that the statements contained therein were false and misleading.” Complaint, ¶ 14. According to Plaintiff, Ms. Putz violated the Fourth Amendment because she signed the Forfeiture Complaint when she would have had access to information and data showing that the chemical compounds at issue in LG’s products were safe and would have fallen within approved or exempted categories of dietary ingredients or supplements under the FDA, contradicting what was alleged about the chemical compounds in the Forfeiture Complaint. Specifically, LG alleges that Putz knew that “[t]he FDA had previously classified ATD as a dietary ingredient” and “did not classify this compound as an

unapproved food additive,” but “ignored this information when she verified the complaint for forfeiture.” *See* Plaintiff’s Response Brief, p. 3. LG also states that Ms. Putz “mislead the Court when she verified” that 6-OXO was a new dietary ingredient. *Id.* LG claims that it was because of Ms. Putz’s verification of the allegations its products were removed from sale, and it continues to suffer economic losses therefrom. Complaint, ¶ 42. The Government now moves to dismiss LG’s Complaint in this action.

### III. DISCUSSION

#### A. APPLICABLE STANDARDS

Fed. R. Civ. P. 12(b)(6) authorizes the Court to dismiss a complaint if it “fail[s] to state a claim upon which relief can be granted. . . .” In deciding a motion brought under Rule 12(b)(6), the Court must construe the complaint in the light most favorable to the plaintiff and accept all well-pled factual allegations as true. *League of United Latin American Citizens v. Bredesen*, 500 F.3d 523, 527 (6th Cir. 2007). Yet, “the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions.” *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009). Moreover, “[w]hile a complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations, a plaintiff’s obligation to provide the grounds of his entitlement to relief requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do.” *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555, 127 S. Ct. 1955, 1964-65 (2007) (internal quotation marks, alteration, and citations omitted). Rather, to withstand a motion to dismiss, the complaint’s factual allegations, accepted as

true, “must be enough to raise a right to relief above the speculative level,” and to “state a claim to relief that is plausible on its face.” *Twombly*, 550 U.S. at 555, 570, 127 S. Ct. at 1965, 1974. “A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Iqbal*, 129 S. Ct. at 1949.

Pursuant to Fed. R. Civ. P. 12(d), if on a Rule 12(b)(6) motion matters outside the pleadings are presented to the court, the motion must be treated as a motion for summary judgment under Rule 56. However, documents attached to a motion to dismiss that are referred to in the Complaint and central to the claim are deemed to form part of the pleadings. *Greenberg v. Life Ins. Co. of Virginia*, 177 F.3d 507, 514 (6th Cir. 1999); *Armengau v. Cline*, 7 Fed. Appx. 336, 344 (6th Cir. 2001). The Court may also consider “matters of public record,” including court filings and letter decisions of governmental agencies, without converting a Rule 12(b) or (c) motion to dismiss to one for summary judgment. *See Amini v. Oberlin College*, 259 F.3d 493, 502 (6th Cir. 2001); *Jackson v. City of Columbus*, 194 F.3d 737, 745 (6th Cir. 1999), *abrogated on other grounds by Swierkiewicz v. Sorema, N.A.*, 534 U.S. 506 (2002).

In this case, Defendant has attached to her motion and briefs pleadings and documents filed with the court in the Forfeiture Action and FDA Warning Letters concerning the chemical compounds ATD and 6-OXO.<sup>2</sup> These exhibits and the

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<sup>2</sup> Plaintiff attached to its Complaint other FDA warning letters, the Consent Decree entered in the Forfeiture Action, and literature concerning the chemical

information contained therein are matters of public record, are referenced in Plaintiff's Complaint and are central to Plaintiff's claims. As such, they may be considered in deciding Defendants' motion. *Greenberg, supra*. Thus, conversion to a Rule 56 motion is not required.

B. PLAINTIFF'S CLAIMS ARE BARRED BY RES JUDICATA.

*Res judicata*, i.e., the preclusive effect of a judgment, encompasses two distinct doctrines: claim preclusion and issue preclusion. *Taylor v. Sturgell*, 553 U.S. 880, 891–93, 128 S.Ct. 2161, 171 L.Ed.2d 155 (2008). Under the doctrine of claim preclusion, “a final judgment on the merits in an action precludes a party from bringing a subsequent lawsuit on the same claim or raising a new defense to defeat a prior judgment.” *Mitchell v. Chapman*, 343 F.3d 811, 819 (6th Cir.2003). It precludes relitigating a claim previously adjudicated as well as litigating a claim or defense that should have been raised, but was not, in the prior suit. *Id.* See also *Dodrill v. Ludt*, 764 F.2d 442, 443 (6th Cir.1985).

When a previous judgment upon which the defendant bases a *res judicata* argument was issued by a federal court on a federal question, it is necessary to look to federal law to determine the judgment's preclusive effect. *Hamilton's Bogarts, Inc., v. Michigan*, 501 F.3d 644, 650 (6th Cir.2007). “*Res judicata* applies when (1) there is a final decision on the merits of the first action by a court of competent jurisdiction; (2) the second action involves the same parties, or their privies, as the first; (3) the second action raises an issue

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compounds ATD and 6-OXO.

actually litigated or which should have been litigated in the first action; and (4) there is identity of claims.” *Walker v. General Tel. Co.*, 25 F. App’x 332, 336 (6th Cir.2001); *see Sanders Confectionery Prod., Inc. v. Heller Fin., Inc.*, 973 F.2d 474, 480 (6th Cir.1992). Identity of claims means an “identity of the facts creating the right of action and of the evidence necessary to sustain each action.” *Westwood Chem. Co. v. Kulick*, 656 F.2d 1224, 1227 (6th Cir.1981).

Here, there is no question as to the identity of claims -- the same facts essential to the maintenance of the Forfeiture Action are necessary to sustain this action. Facts as asserted in the Forfeiture Complaint verified by Defendant Putz are what gave rise to the seizure of Plaintiff’s products. These same facts are precisely the facts Plaintiff’s Complaint places at issue in this action.

The other three elements that need to be met before *res judicata* will apply: (1) the first action must have been to be decided on the merits, (2) the matter contested in the second case was or could have been resolved in the first case, and (3) both actions involved the same parties or their “privies”, are also satisfied here.

First, the Sixth Circuit has held that a consent decree entered in a prior forfeiture action -- such as the 2009 Consent Decree entered in the LG Forfeiture Action -- is a final decision on the merits for purposes of application of the doctrine of *res judicata*, and barred the plaintiffs in a subsequent civil action bars from litigating the issues involved in the forfeiture action. *See Blakely v. United States*, 276 F.3d 853, 866-868 (6th Cir. 2002); *see also Bayou Fleet, Inc. v. Alexander*, 234 F.3d 852, 858 (5th Cir.2000) (“A consent



judgment, which has been freely negotiated by the parties and has been approved by the court, has the full effect of final judgment for purposes of claim preclusion.”) By entering into a consent decree in the forfeiture action, the “parties waive their right to litigate the issues involved in the case. . . .” *Blakely* at 868, *quoting United States v. Armour & Co.*, 402 U.S. 673, 681, 91 S.Ct. 1752 (1971).

Second, the matter contested in this action -- the veracity of the Forfeiture Complaint allegations verified by Defendant Putz -- was contested in the Forfeiture Action. LG specifically challenged the veracity of the allegations in responding to the complaint in the Forfeiture Action. *See* LG’s Answer and Affirmative Defenses, Forfeiture Action Dkt. #3. That LG denied the complaint allegations in agreeing to the Consent Decree does not alter the fact that LG *did* contest them in the Forfeiture Action and could have continued to litigate the issues but elected to avoid further litigation and resolve the matter by way of a consent decree agreeing to the products’ destruction.<sup>3</sup> Furthermore, LG filed a counterclaim against the FDA, which it later voluntarily dismissed when the Government advised that it would move for dismissal on the grounds of sovereign immunity. However, nothing precluded LG from impleading Defendant Putz as a third-party defendant and proceeding with a claim for damages against Putz.

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<sup>3</sup> In fact, the Supreme Court has held that the proper forum to challenge a probable cause determination with respect to a civil forfeiture is during the forfeiture proceeding. *See Ewing v. Mytinger & Casselberry, Inc.*, 339 U.S. 594, 600-01 (1950) (“[T]he only review of the issue of probable cause Congress granted was the one provided in the libel suit.”) The Supreme Court has also confirmed the adequacy of this procedure, stating that the opportunity to challenge the probable cause determination during the forfeiture proceedings is sufficient to satisfy due process. *Id.* at 558-59.

Finally, both actions involved the same parties or their privies. The test for privity among the parties is met when the parties stand in an employer-employee relationship. See *McCoy v. Michigan*, 2010 WL 841198, at \*3 (6th Cir.2010); *see also Coatney v. City of Dearborn*, 2009 WL 322032, at \*3 (E.D.Mich. 2009) (holding that employees of the defendant city were in privity with the city); *ABS Industries, Inc. v. Fifth Third Bank*, 333 Fed.Appx. 994, 999-1000 (6th Cir.2009) (“[I]t is well settled that a principal-agent relationship satisfies the privity requirement of *res judicata* where the claims alleged are within the scope of the agency relationship.”). Defendant Putz is an employee of the United States Food and Drug Administration, U.S. Department of Health and Human Services, LG’s opposing party in the Forfeiture Action. Therefore, the identity of the parties requirement for application of *res judicata* is satisfied.

All of the elements being satisfied for application of the doctrine of *res judicata*, Plaintiff LG is precluded from litigating the issues it raises in its Complaint in this action.

#### C. DEFENDANT IS CLOAKED WITH QUALIFIED IMMUNITY

To the extent that *res judicata* does not bar Plaintiff’s action, Defendant Putz is shielded by qualified immunity.

Qualified immunity shields public officials who perform discretionary functions from the necessity of defending against tort liability so long as their conduct does not violate clearly established rights of which a reasonable official would have known. *See Fisher v. Harden*, 398 F.3d 837, 842 (6th Cir. 2005). The doctrine is designed to avoid

excessive disruption of government and permit the resolution of many insubstantial claims on a motion to dismiss or for summary judgment. *Harlow v. Fitzgerald*, 452 U.S. 800, 818 (1982); *English v. Dyke*, 23 F.3d 1086, 1089 (6th Cir. 1994). It protects “all but the plainly incompetent or those who knowingly violate the law.” *Malley v. Briggs*, 475 U.S. 353, 341 (1986). Qualified immunity is an affirmative defense; once asserted, the “burden of proof is on the plaintiff to show that the defendant is not entitled to qualified immunity.” *Armstrong v. City of Melvindale*, 432 F.3d 695, 699 (6th Cir. 2006) (citing *Sheets v. Mullins*, 287 F.3d 581, 586 (6th cir. 2002)).

Whether qualified immunity applies turns on the “objective legal reasonableness” of the official’s action, viewed on a fact-specific, case-by-case basis. *Id.* (citing *O’Brien v. City of Grand Rapids*, 23 F.3d 990, 999 (6th Cir. 1994)). To analyze claims of qualified immunity, the court uses a two-part test “(1) whether, considering the allegations in a light most favorable to the party injured, a constitutional right has been violated, and (2) whether that right was clearly established.” *Estate of Carter v. City of Detroit*, 408 F.3d 305, 310-11 (6th Cir. 2005) (citing *Saucier v. Katz*, 533 U.S. 194, 201 (2001)). Courts have discretion in deciding which of these two prongs should be considered first. *Person v. Callahan*, 129 S.Ct. 808, 818 (2009).

With respect to the constitutional right alleged to have been violated, “[t]he contours of the right must be sufficiently clear that a reasonable official would understand that what he is doing violates that right.” *Anderson v. Creighton*, 483 U.S.

635, 640, 107 S.Ct. 3034 (1987). If the controlling law is not clearly established, an official cannot be liable, because “a reasonable person would not be expected to know how to structure his conduct to avoid liability.” *Mendoza v. Block*, 27 F.3d 1357, 1361 (9th Cir. 1994).

In the context of an unconstitutional warrant, an official “will not be immune if . . . it is obvious that no reasonably competent officer would have concluded that a warrant should issue; but if officers of reasonable competence could disagree on this issue, immunity should be recognized.” *Malley*, 475 U.S. at 341, 106 S.Ct. 1092. Put another way, if there can be reasonable disagreement, then the right cannot be considered “clearly established.” Accordingly, to be entitled to qualified immunity, Defendant was only required to “exercise reasonable professional judgment” in applying for the warrant. *Id.* at 346, 106 S.Ct. 1092.

LG argues that its Fourth Amendment rights were violated when Defendant Putz provided “false and misleading” information in the Complaint for the seizure and forfeiture of LG’s products. However the only alleged “false statement” alleged is Defendant Putz’s interpretation of the Federal Food and Drug Act in accordance with the FDA’s position on ATD and 6-OXO in verifying in the Forfeiture Complaint that ATD and 6-OXO were unapproved additives and/or new dietary ingredients. *See* Complaint, ¶¶ 20-21. LG contends that its interpretation of the Act was correct and that Defendant Putz should have known that the FDA’s position was incorrect. However, neither the Fourth Amendment nor any other provision of the Constitution requires the FDA to

accept LG's alternative interpretation of the Act. Accordingly, LG's claim fails to establish clearly that a constitutional right is at issue here.

CONCLUSION

For the foregoing reasons,

IT IS HEREBY ORDERED that Defendant's Motion to Dismiss [**Dkt. # 13**] is GRANTED and Plaintiff's Complaint is DISMISSED, in its entirety, with prejudice.

Let Judgment be entered accordingly.

s/Gerald E. Rosen  
Chief Judge, United States District Court

Dated: March 30, 2012

I hereby certify that a copy of the foregoing document was served upon counsel of record on April 2, 2012, by electronic and/or ordinary mail.

s/Ruth A. Gunther  
Case Manager